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UTILITY PATENT APPLICATION TRANSMITTAL AND FEE SHEET

Transmitted herewith for filing under 37 CFR §1.53(b) is the utility patent application of

Applicant (or identifier): KIS ET AL.

Title: PACKAGE FOR A PHARMACEUTICAL PRODUCT

Enclosed are:

1. ☒ Specification (Including Claims and Abstract) - 10 pages
2. ☐ Drawings - sheets
3. ☒ Executed Declaration and Power of Attorney (original or copy)
4. ☐ Microfiche Computer Program (appendix)
5. Nucleotide and/or Amino Acid Sequence Submission
   - ☐ Computer Readable Copy
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6. ☒ Preliminary Amendment
7. ☐ Assignment Papers (Cover Sheet & Document(s))
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Basic Filing Fee								$ 690
Multiple Dependent Claim Fee ($ 260)								$
Foreign Language Surcharge ($ 130)								$
	For	Number Filed		Number Extra		Rate		
Extra Claims	Total Claims	13	-20	0	x	$ 18	=	$
	Independent Claims	2	-3	0	x	$ 78	=	$
						TOTAL FILING FEE		$ 690

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Please address all correspondence to the address associated with Customer No. 001095, which is currently:

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Please direct all telephone calls to the undersigned at the number given below, and all telefaxes to (678) 415-3068.

Respectfully submitted,

Date: May 26, 2000

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CASE OP/V-30969A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

KIS ET AL.

APPLICATION NO:

FILED: MAY 26, 2000

FOR: PACKAGE FOR A PHARMACEUTICAL PRODUCT

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Please cancel Claim 5 and amend claims 1, 3 – 4, 6 – 9, and 13 – 14 as follows:

1. A package for a pharmaceutical product[, particularly a liquid ophthalmic composition, such as an ophthalmic solution, gel or ointment, for example a tube or a dropper bottle assembly used to dispense said product], wherein said package is made of [a specific form of] polypropylene and wherein said package shows after an autoclaving processing of at least 121 ^{O}C and for at least 20 minutes no deformation such as shrinkage or blowing-up and retains a sufficient high squeezability in order to dispense said product.

3. Package of claim 1 [or 2], wherein said package comprises a plastic bottle [(2)] for holding said product to be dispensed, a plastic nozzle tip [(3)] for dispensing said product and a cap [(5)] for closing said bottle.

4. A package according to claim 3, wherein said bottle [(2)] having a neck portion [(4)] that includes an externally threaded portion [(15)] and an outer rim which defines an outlet of the bottle, and said nozzle tip [(3)] being in fluid contact with said outlet of said bottle and having an dispensing passageway [(7)] for allowing liquid within said bottle [(2)] to pass out of an outlet [(8)] of said nozzle tip [(3)], and said cap [(5)] having internal threads for engagement with said externally threaded portion [(15)] of said neck portion [(4)].

6. A package according to claim [3 - 5], wherein said bottle [(2)] is made of Appryl 3020 SM 3, the nozzle tip [(3)] is made of Appryl 3020 SM 3, and the cap [(5)] is made of HDPE GC 7260 or of low density polyethylene.

7. A package according to [any of claims 3 to 6] Claim 3, wherein the bottom [(12)] of the bottle [(2)] has a concave configuration.

8. A package according to [any of claims 1 to 7] Claim 1, wherein the wall thickness of the package, particularly the bottle [(2)] is in the range of 0.3 mm to 0.6 mm.

9. A package according to [any of claims 1 to 8] Claim 1, wherein the wall thickness of the package, particularly the bottle [(2)] is 0.45 mm.

13. Method of claim 10, wherein said package is a [bottle, more preferably a] PP-bottle.

14. Package of claim [5 - 9] 6, wherein the physical chemical properties of said polypropylene meet the requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997).

Respectfully submitted,

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Robert J. Gorman, Jr.
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Reg. No. 41,789

Date: 26 May 2000

Package for a pharmaceutical product

The invention relates to a package for a pharmaceutical product, particularly a tube or a dropper bottle assembly used to dispense liquids, aerosols or strings, and a method of sterilizing said package.

Particularly dropper bottle assemblies are used to dispense a variety of liquids, typically one drop at a time. For example, the dispensing of a liquid reagent used in laboratories, dispensing eye medication, dispensing ear medication, dispensing nose medication, or in any other environment where dispensing of a liquid in controlled drop increments is desired.

A typical prior art bottle assembly comprises a plastic squeeze bottle, a nozzle tip or dropper which is snap fit into the bottle and a cap or closure which is threaded onto the bottle. Liquid is dispensed one drop at a time by squeezing the bottle so as to force liquid out the end of the nozzle tip. The bottle, the nozzle tip and the cap are made of low density polyethylene because this material has a high enough modulus of elasticity for squeezing the cylindrical sidewall of the bottle with one's fingers which causes the liquid therein to pass through a passageway.

For filling the bottle with a pharmaceutical product, particularly an ophthalmic liquid which has to fulfill the conditions concerning sterility, it is state of the art to filtrate and to sterilize the solution or liquid which should be filled into the bottles by filtration or autoclaving. Also the bottles, the nozzle tips and the caps are sterilized, e.g. by ethylene oxide treatment, UV, gamma or electron beam irradiation. The filling of the bottles takes place in aseptic room conditions. However, after filling the bottles, inserting the nozzle tip into the neck portion and threading the cap onto the bottle no further sterilization will proceed. The filled and closed bottles are removed from the aseptic area. The aseptic area is normally a room which stands under slight excess air pressure and the entrance and the exit of the room are constructed as sluices.

A pharmaceutical product as used hereinbefore or hereinafter is understood to relate in particular to a pharmaceutical composition, which is preferably an aqueous and/or a non-aqueous pharmaceutical composition or a mixture of a non-aqueous and an aqueous pharmaceutical composition, which is preferably a liquid solution, a gel or an ointment,

wherein pharmaceutical relates preferably to an ophthalmic, an otic and/or a nasal administration.

However, the standard method of filling bottles with pharmaceutical substances, particularly with ophthalmic solutions and gels does not fulfill the European Pharmacopoeia, 3rd. edition (1997) e.g. page 283, and/or the EU regulation (Committee of Proprietory Medicinal Products [CPMP] , Section 5, Manufacturing Process, Note for Guidance). According to this regulation, an ophthalmic pharmaceutical liquid or gel should be terminally sterilized in their final container for achieving the highest level of sterility assurance, if ever possible. But using for sterilization an autoclaving method with a temperature of at least 121 °C for at least 15 minutes for the low density polyethylene bottles known in the prior art deformation, e.g. shrinkage or blowing up occur and the bottles have lost their elasticity so that they are damaged or partly molten and not squeezable anymore.

The invention addresses the problem of providing a pharmaceutical package, particularly a bottle assembly or a tube filled with a pharmaceutical product, particularly an ophthalmic solution or gel, meets the requirements of the European Pharmacopoeia regulation and/or EU-regulation without any significant deformation and retaining a sufficient squeezibility for dispensing the liquid after the autoclaving proceedings.

The invention solves this problem with the features indicated in both claim 1 and 10. With regard to further substantial design features, reference is made to the dependent claims.

The use of a specific form of polypropylene for the material of the package enables to fulfill the European Pharmacopoeia regulation and/or EU regulation. Packages made of a specific form of polypropylene are heat-resistant and retain their formation and their squeezing characteristics after the autoclaving processing. Therefore, the consumer can easily dispense one drop at a time by squeezing the package so as to force the pharmaceutical product out of the package. Particularly the invention provides a tube or a dropper bottle assembly with a high enough squeezibility for dispensing an ophthalmic solution or gel by compressing the tube or bottle.

Further details and advantages of the invention are apparent from the following description and drawings. The drawings show:

Fig. 2 a front view of a dropper bottle assembly as an example of the invention;

Fig. 2 a front view, partially in cross section of a dropper bottle assembly in Fig. 1;

Fig. 3 a diagram of the temperature and the pressure run in the autoclaving chamber during the autoclaving processing for a 5 ml bottle;

Fig. 4 a diagram of the temperature and the pressure run in the autoclaving chamber during the autoclaving processing for a 10 ml bottle;

Fig. 5 a test diagram which shows the power as a function of the elasticity for a 5 ml bottle;

Fig. 6 a test diagram which shows the power as a function of the elasticity for a 10 ml bottle.

Referring to Fig. 1 and Fig. 2, there is illustrated as an example of the invention a dropper bottle assembly 1 which comprises a squeeze bottle 2 having a nozzle tip 3 designed to snap fit within the neck portion 4 of the bottle 2, and a cap 5 designed to fit over the nozzle tip 3 and engage threaded portion 6 of the neck portion 4. The nozzle tip 3 has a passageway 7 for allowing fluid within the bottle 2 to be dispensed through outlet 8. Liquid is dispensed by first removing cap 5 and then squeezing the cylindrical sidewall 9 of bottle 2 with one's fingers which causes the liquid therein to pass through a passageway 7. For safety purposes the bottle assembly is further provided with either a shrink collar or with a temper resistance ring 10.

The bottle 2 is made of a specific form of polypropylene, particularly a polypropylene of the type Appryl 3020 SM 3. In comparison with the prior art the bottle 2 has a similar shape with the exception that the bottom 12 has advantageously a concave configuration. This is in particular for avoiding deformation, e.g. shrinkage or blowing-up, of the bottle during the autoclaving processing. Due to the concave configuration the degree of pressure necessary

to cause deformation of the bottom is much higher. Naturally, other indentation, grooves, slits or slots can be designed at the bottom 12 or the sidewall 9 to give the bottle 2 a greater stability during the autoclaving processing. The nozzle tip 3 is also particularly formed of a specific form of polypropylene, particularly a polypropylene of the type Appryl 3020 SM 3. There occur no problems during the autoclaving processing which could generate leakage problems. Rather, by using the same material for the bottle 3 and the nozzle tip 3 the two components are sealed a little bit together during the autoclaving processing. Furthermore, as polypropylene is a quite rigid material and it is more difficult to snap fit the nozzle tip 3 into the neck portion 4 of the bottle 2, the nozzle tip 3 has a special configuration to ensure a good seal between the bottle 2 and the nozzle tip 3. The sealing part 13 of the nozzle tip 3 used for sticking the nozzle tip 3 into the neck portion 4 of the bottle 2 is formed in the upper part nearly cylindrical whereas the lower part has the form of a taper shank. As a stopping face the sealing part 13 of the nozzle tip 3 is provided with a collar 14. The cap 5 is threaded on the neck portion 4 of the bottle 2 having external threads 6. The cap 5 as the closure of the bottle assembly is particularly formed of a high density polyethylene, particularly of HDPE GC 7260. The cap 5 can also be made of polypropylene, however in this case during the autoclaving processing a sealing between the nozzle tip 3 and the cap 5 can occur, so that it is quite difficult to open the bottle 2 or the nozzle tip 3 is damaged after opening of the bottle 2. If the cap 5 is made of another material than polypropylene, particularly of high density polyethylene, the risk of a sealing or other damages can be avoided as these two materials have a different modulus of elasticity.

The wall thickness of the PP bottle is typically in the range of 0.3 mm to 0.6 mm, preferably 0.45 mm. If the wall thickness is too thin, then the stability of the bottle decreases. However, if the wall thickness is too thick, then the squeezability of the bottle decreases and the bottle becomes too rigid. Indeed, the preferable value of the wall thickness is lower than in comparison with the prior art PE bottles, so that there is much lesser material necessary for molding the bottles, preferably by an injection molding process.

When the package of the present invention relates to a tube, the material may also be a so-called laminated PP-foil (polyfoil tube) exhibiting a sandwich-type structure. Typically such a laminated foil contain one or more layers of polypropylene (PP), preferably two (e.g. a top and a bottom layer), and one or more layers of aluminum, preferably one (e.g. the middle layer). Said laminated material provides typically enhanced stability.

Further, it is advantageous to adjust the autoclaving processing to the PP-bottles to avoid damages as shrinkage or blowing-up. After filling the bottles with the pharmaceutical liquid or gel, particularly an ophthalmic liquid or gel, the closed bottles are introduced into an autoclaving chamber. In the context of the present application filling of the bottles denotes typically a normal filling, such that for example in the upper part of said bottle some air will remain. As the whole bottles will be sterilized it is not anymore necessary that the filling and closing of the bottles has to take place under aseptic conditions. As it is known in the prior art, such an autoclaving chamber works with steam. The temperature and the pressure run in the chamber as a function of time is demonstrated in Fig. 3 and 4. The chamber contains typically one or more nozzles for the steam entrance and typically several sensors for temperature monitoring. Advantageously the temperature can be adjusted very quickly if some corrections might be necessary.

Further, particularly the chamber is provided with a pressure device for generating a counter pressure in the autoclaving chamber. Also the pressure can be adjusted very quickly if some corrections might be necessary. Preferably, the counter pressure is regulated electronically via computer control. Said pressure set-up is advantageously used for avoiding a blowing-up of the bottles. After introducing the bottles into the chamber, the temperature rises typically from room temperature to 121 ^{o}C and the pressure rises typically from atmospheric pressure to a maximum value which is characteristic for the sterilization process. Typically, the choice of the pressure value depends on the form of the bottles.

Fig. 4 shows in an exemplary fashion the adjusted pressure with a value of 2700 mbar is lower for the 5 ml bottles than for the 10 ml bottles with a value of 3200 mbar. As the 5 ml bottles are more rigid in comparison to the 10 ml bottles a lower pressure value is necessary to avoid blowing up of the bottles. In the beginning of the autoclaving process the increasing of the temperature is quite steep, whereas the gradient of the pressure remains nearly constant up to reaching the maximum value. During the sterilization the values of the temperature and the pressure maintain constant. After the sterilization both the temperature and the pressure decreases continuously. The autoclaving processing takes as a whole nearly one hour. After reaching again room temperature and atmospheric pressure the chamber will be opened for taking out the sterilized bottles.

Several test programs have shown that after an autoclaving procedure of a temperature of 121 °C during 20 minutes with an autoclaving procedure according to the above described diagrams no deformation, e.g. shrinkage or blowing-up of the PP bottle assembly could be observed. Two diagrams demonstrating the squeezability of a bottle assembly with a volume of 5 ml and of 10 ml are shown in Fig. 5 and Fig. 6. To achieve typically a compression of 2 mm in comparison to the normal dimension of the bottle, typically a power value of about 9 N is necessary for a 5 ml PP-bottle. For a 10 ml PP bottle, typically a power value of about 14 N is required. For comparative purposes it should be mentioned that prior art PE bottles exhibit typically a similar squeezability, e.g. the 5 ml PE bottle slightly less, the 10 ml PE-bottles a little bit more power. For the consumer these values are virtually equivalent.

Further tests concerning the tightness of the bottles before and after the autoclaving procedure show compliance with the regulations for pharmaceuticals. Tests concerning the O_2-barrier and the H_20-barrier properties of the bottles in accordance to the invention (despite of thinner walls) after stress storage during 4 weeks at 80 °C show no difference to the PE-bottles known from the prior art. Furthermore, tests in respect to bacteria toxicity show that no toxicity could be demonstrated for the PP-bottles. PE-bottles known from the prior art are typically twice as thick as the PP-package (PP-bottles) of the present invention.

Therefore, the invention provides a package particularly a tube or a dropper bottle assembly for pharmaceutical products, especially for ophthalmic pharmaceutical solutions and gels which can be sterilized as a whole after filling the product into the package by an autoclaving process in accordance to the invention. The package retains after the autoclaving procedure its sqeezability which is important for the consumer for dispensing especially a solution or gel out of the package. Furthermore, no deformation could be observed after having exposed said package to an autoclaving process in accordance to the invention. This means that a package according to the invention, especially a dropper bottle assembly filled with an ophthalmic solution, gel or ointment, fulfills the European Pharmacopoeia, 3rd. edition (1997), and/or the EU regulation mentioned above, which ensure a higher level of safety.

In addition, the PP-material used for fabricating the package in accordance to the invention exhibits physical chemical properties which meet the requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997). This is in particular applicable to the additives comprised in the PP-material in accordance to the invention.

Claims

1. A package for a pharmaceutical product, particularly a liquid ophthalmic composition, such as an ophthalmic solution, gel or ointment, for example a tube or a dropper bottle assembly used to dispense said product, wherein said package is made of a specific form of polypropylene and wherein said package shows after an autoclaving processing of at least 121 ^{o}C and for at least 20 minutes no deformation such as shrinkage or blowing-up and retains a sufficient high squeezability in order to dispense said product.

2. A package according to claim 1, wherein said package meets the requirements of the European Pharmacopoeia, 3rd. edition (1997) and the EU-regulation.

3. Package of claim 1 or 2, wherein said package comprises a plastic bottle (2) for holding said product to be dispensed, a plastic nozzle tip (3) for dispensing said product and a cap (5) for closing said bottle.

4. A package according to claim 3, wherein said bottle (2) having a neck portion (4) that includes an externally threaded portion (15) and an outer rim which defines an outlet of the bottle, and said nozzle tip (3) being in fluid contact with said outlet of said bottle and having an dispensing passageway (7) for allowing liquid within said bottle (2) to pass out of an outlet (8) of said nozzle tip (3), and said cap (5) having internal threads for engagement with said externally threaded portion (15) of said neck portion (4).

5. A package according to claim 3 - 4, wherein said bottle (2) is made of a specific form of polypropylene, the nozzle tip (3) is made of a specific form of polypropylene and the cap (5) is made of a specific form of polypropylene and/or of high density polyethylene.

6. A package according to claim 3 - 5, wherein said bottle (2) is made of Appryl 3020 SM 3, the nozzle tip (3) is made of Appryl 3020 SM 3, and the cap (5) is made of HDPE GC 7260 or of polypropylene.

7. A package according to any of claims 3 to 6, wherein the bottom (12) of the bottle (2) has a concave configuration.

8. A package according to any of claims 1 to 7, wherein the wall thickness of the package, particularly the bottle (2) is in the range of 0.3 mm to 0.6 mm.

9. A package according to any of claims 1 to 8, wherein the wall thickness of the package, particularly the bottle (2) is 0.45 mm.

10. Method for sterilizing a pharmaceutical package comprising the steps,
placing closed package into an autoclaving chamber,
adjusting the temperature and the pressure in said chamber as a function of time in accordance to the prerequisites of the material of said package,
wherein a counter pressure is generated in said chamber and wherein this is regulated electronically via computer control, and
wherein said counter pressure avoids a deformation such as a blowing-up of said package.

11. Method of claim 10, wherein the pressure value is adjusted to the size of the packages to be sterilized.

12. Method of claim 10, wherein the pressure value is adjusted to the type of polypropylene.

13. Method of claim 10, wherein said package is a bottle, more preferably a PP-bottle.

14. Package of claim 5 - 9, wherein the physical chemical properties of said polypropylene meet the requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997).

Abstract

The invention relates to a package for a pharmaceutical product, particularly a tube or a dropper bottle assembly used to dispense liquids, aerosols or strings, and a method of sterilizing said package.

DECLARATION AND POWER OF ATTORNEY FOR UNITED STATES PATENT APPLICATION

☒ Original ☐ Supplemental ☐ Substitute

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a United States patent is sought on the invention entitled

Package for a pharmaceutical product

the specification of which:

☒ is attached hereto.

☐ was filed on _____ (day/month/year) as Application No. _____

and, if this box (☐) contains an ✖

☐ was amended on _____ (day/month/year)

☐ was filed as Patent Cooperation Treaty international Application No.

_____ on _____ (day/month/year)

and, if this box (☐) contains an ✖

☐ entered the national stage in the United States and was accorded Application No.

_____

and, if this box (☐) contains an ✖

☐ was amended, subsequent to entry into the national stage, on _____ (day/month/year)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above and, if this application was filed as a Patent Cooperation Treaty international application, by any amendments made during the international stage (including any made under Patent Cooperation Treaty Rule 91, Article 19 and Article 34).

I acknowledge my duty to disclose all information which is known by me to be material to the patentability of this application as defined in 37 C.F.R. § 1.56.

I hereby claim the benefit under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate listed below and under 35 U.S.C. §365(a) of any Patent Cooperation Treaty international application(s) designating at least one country other than the United States listed below and have also listed below any foreign application(s) for patent or inventor's certificate and Patent Cooperation Treaty international application(s) designating at least one country other than the United States for the same subject matter and having a filing date before that of the application the priority of which is claimed for that subject matter:

COUNTRY/REGION (OR P.C.T.)	APPLICATION No.	FILING DATE (day/month/year)	PRIORITY CLAIMED
European Patent Application	**99110355.7**	**28/05/1999**	☒ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

I hereby claim the benefit under 35 U.S.C. § 119 (e) of any United States provisional application(s) listed below:

APPLICATION NO.	FILING DATE (day/month/year)

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) listed below and under 35 U.S.C. §365(c) of any Patent Cooperation Treaty international application(s) designating the United States listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in said prior application(s) in the manner required by the first paragraph of 35 U.S.C. §112, I acknowledge my duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date(s) of the prior application(s) and the national or Patent Cooperation Treaty international filing date of this application:

United States Application No.	United States Filing Date (day/month/year)	Status (Pending, Abandoned or U.S. Patent No.)	International Application No. and Filing Date

I hereby appoint the registered practitioners associated with Customer No. 001095, respectively and individually, as my attorneys and agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

If these brackets contain an X [X], I hereby authorize the registered practitioners associated with Customer No. 001095 and any others acting on my behalf to take any action relating to this application based on communications from the Patents and Trademarks Division of Novartis Services AG, Basle, Switzerland, or an affiliate thereof or a successor thereto, without direct communication from me.

Please address all communications to Thomas Hoxie, Novartis Pharmaceuticals Corporation, Patent and Trademark Department, 564 Morris Avenue, Summit, NJ 07901-1027.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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Inventor's signature: György Lajos Kis Date: 14. March 2000 (day/month/year)

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IMPORTANT: Before this declaration is signed, the patent application (the specification, the claims and this declaration) must be read and understood by each person signing it, and no changes may be made in the application after this declaration has been signed.

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Inventor's signature: Eckhard Kräutler Date: 14. März 2000 (day/month/year)

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Full name of third joint inventor, if any

Inventor's signature _____ Date _____ (day/month/year)

Residence

Citizenship

Post Office Address

Full name of fourth joint inventor, if any

Inventor's signature _____ Date _____ (day/month/year)

Residence

Citizenship

Post Office Address